

- Appln. No. 10/673,487
Amd. dated November 4, 2005
Reply to Office Action of July 6, 2005

REMARKS

Claims 1-6 and 13-17 currently appear in this application. The Office Action of July 6, 2005, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Election/Restriction

It is noted that the election requirement has been made final. Accordingly, claims 7-12 have been cancelled and new claims 13-17 submitted in order better to define the invention.

Rejections under 35 U.S.C. 112

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner's position is that the subject matter of claims 7-1, *i.e.*, "evoking a receptor potential in response to photostimulation in the optic nerve" and "an organic dye compound" without limitation, was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It is respectfully submitted that this rejection is now moot, as claim 7-12 have been replaced by new claims 13-17. Support for claims 13-17 can be found in the

specification as filed at page 12, line 17 to page 14, line 19 and page 19, line 7 to page 20, line 2.

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification is said to be enabling for the instant methods of treating dyschromatopsia, but does not reasonably provide enablement for a method of evoking a receptor potential other than dyschromatopsia or claimed compounds other than formulae 1-17.

This rejection is now moot, as claims 7-12 have been replaced by new claims 13-17. New claim 13 recites "an ophthalmologically acceptable organic dye compound." However, it should be noted that the recited "ophthalmologically acceptable organic dye compound" is defined as one "having an absorption maximum in the visible region and being capable of evoking a receptor potential in response to photostimulation in an optic nerve." It is there believed that "an ophthalmologically acceptable organic dye compound" clearly defines the invention. The specification provides a detailed explanation of the compounds at pages 4-11 and pages 16-19. In particular, the examples at pages 16-19 disclose polymethine organic dyes which can be used in the herein claimed invention, such as NK-2761, NK-5962, NK-3041 and NK-3630. The examples confirm that these polymethine organic dyes are capable or evoking a receptor potential, which demonstrates the utility of the present invention.

In support of the above, submitted herewith is a declaration of Dr. Toshihiko MATSUO, one of the inventors of the present application, and a copy of "A Simple Method for Screening Photoelectric Dyes Toward Their Use for Retinal

Prostheses," *Acta. Med. Okayama* vol. 57 No. 5, 2003, pp. 257-260, authored by Dr. Toshihiko MATSUO.

Art Rejections

Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Momose-Sato et al., *Journal of Membrane Biology* (1999), 172(2): 145-157 or Koshiishi et al., U.S. Patent No. 5,132,095.

This rejection is respectfully traversed. It is respectfully submitted that none of these documents discloses or suggests the invention as claimed in claims 13-17.

Momose-Sato, as is evident from the title "Evaluation of Voltage-Sensitive Dyes for Long-Term Recording of Neural Activity in the Hippocampus", and the explanation in the introduction that this article, is concerned with analyzing cellular mechanisms responsible for the phenomena of learning and memory. Momose-Sato discloses a voltage-sensitive dye for recording neural electrical activity at the hippocampus for a relatively long period of time outside a living body.

In contrast to this, claim 13 relates to an artificial material which can substitute for a part or the whole of the function of retinase in animals, including humans, which is administered into a living body. This artificial material comprising "an ophthalmologically acceptable organic dye compound" is used to evoke receptor potential in the optic nerve of patients suffering from visual disorders, such as narrowing of the visual field, visual reduction, nyctalopia, and dyschromatopsia. There is nothing Momose-Sato relating to providing a substitute for part of the

retina. Even if, *arguendo*, Momose-Sato disclosed using the same compounds as those of the present invention, Momose-Sato discloses a completely different application for the dyes, and never suggests that the dye can be used for artificial retinase.

As proof of the utility of the present invention, submitted herewith is the declaration of Dr. Toshishiko MATSUO, one of the inventors. As shown in his *curriculum vitae* attached to the declaration, Dr. MATSUO is a medical doctor as well as vice chair in ophthalmology at Okayama University Hospital. As stated in paragraph 8 of the declaration, the present invention presents a breakthrough in the field of retinal prostheses because it has a high potential of giving "a light" to patients who need treatment for hereditary and acquired disease accompanied by loss of photoreceptor cells, such as retinitis pigmentosa. In fact, a letter of gratitude from members of the Osaka Prefecture Section of the Japan Retinitis Pigmentosa Society was given to Dr. MATSUO for advancement of his research in dye-coupled retinal prostheses.

Koshiishi et al. disclose dye compounds used as materials for an optical sensor which detects potassium ion, calcium ion, sodium ion, lithium ion, or magnesium ion. In contrast thereto, the invention claimed herein relates to an artificial retinase for animals, including humans. Therefore, it is respectfully submitted that the subject matter of Koshiishi et al. and the present invention are completely different. Koshiishi et al. have nothing to do with the present invention.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Momose-Sato et al. The Examiner's position is that Applicants claim a method of using organic dye compounds to evoke a receptor in response to photostimulation. The Examiner alleges that the claimed compounds would be expected to possess similar activities from the known Momose-Sato et al. compounds.

This rejection is respectfully traversed. Momose-Sato et al. disclose voltage-sensitive dyes for optical measurements of neural activity in the hippocampal slice. The present invention, however, is directed to compounds that can be used as artificial retinase. The evaluation process of Momose-Sato et al. has nothing at all to do with the present invention as claims in claims 13-17.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koshiishi et al. The Examiner's position is that Koshiishi et al. disclose a compound of a formula similar to applicant's compounds used as a dye for an optical sensor.

This rejection is respectfully traversed. The compounds of Koshiishi et al. are used as materials for an optical sensor for detecting metal ions. The herein claimed invention, however, relates to an artificial retinase for use in animals. There is nothing in Koshiishi et al. that even suggests the present invention.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable consideration is earnestly solicited.

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Respectfully submitted,

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